

Abstracts

A55

change in weight measured by BMI and raw weight in elderly T2DM patients in a real-world setting. The likelihood of weight loss in OAD users was somewhat consistent with the literature.

PDB4

PREVALENCE OF RENAL INSUFFICIENCY IN A COMMERCIAL-INSURED POPULATION WITH TYPE 2 DIABETES MELLITUS ENROLLED IN A LARGE, US NATIONAL HEALTH PLAN

Burke JP¹, Sander S², Parker M³, Moran HJ⁴, Thayer S⁵

¹3 Innovus, Eden Prairie, MN, USA, ²Boehringer Ingelheim Pharmaceuticals, Inc, Ridgefield, CT, USA, ³Boehringer-Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA, ⁴3 Global, Cary, NC, USA, ⁵3 Innovus, San Francisco, CA, USA

OBJECTIVES: Renal insufficiency (RI), a common complication of type 2 diabetes mellitus (T2DM), is associated with increased morbidity, mortality and costs. Early and accurate detection of RI among patients with T2DM is essential in delaying or reducing these outcomes. Consensus guidelines advocate the use of estimated glomerular filtration rate (eGFR) to assess renal function. The objective of this retrospective database analysis was to evaluate the prevalence of RI in a commercially-insured population with T2DM using ICD-9-CM codes and laboratory data from a large, national US health plan. **METHODS:** The study sample consisted of commercially-insured health plan members ≥ 18 years of age with evidence of T2DM from 1/1/06–12/31/07 and continuous enrollment for 12 months before and after identification of T2DM. The prevalence of RI was determined by physician diagnosis using ICD-9-CM codes (“physician-diagnosed”), and eGFR calculation using serum creatinine (SCr), age and gender (“eGFR-diagnosed”). Approximately 26.8% of members had laboratory data (≥ 1 SCr value) after identification; physician-diagnosed and eGFR-diagnosed RI prevalences were identified in this subset. RI was identified using the National Kidney Foundation (NKF) 5-stage classification system and defined as \geq stage 2, or an eGFR of ≤ 89 ml/min. Comparisons between cohorts were made using chi-squares. **RESULTS:** Among over 13.7 million commercially-insured members within the database, 664,619 (4.8%) had evidence of T2DM. The sample included 259,295 members after applying continuous enrollment and other study criteria, of which 20,914 (9.2%) had evidence of physician-diagnosed RI. Among the subset with laboratory data available ($n = 69,439$), 6,795 (9.8%) had physician-diagnosed RI while 17,981 (25.9%) had evidence of eGFR-diagnosed RI ($p < 0.001$). **CONCLUSIONS:** The prevalence of RI within a commercially-insured population with T2DM was significantly higher using eGFR, the recommended method of estimating RI, than physician diagnosis of RI. It is likely that RI in the commercially-insured is under-estimated using diagnosis codes in claims data.

PDB5

GLYCAEMIC CONTROL AND INSULIN UTILIZATION IN UK PATIENTS WITH TYPE 2 DIABETES INITIATED ON EITHER BIPHASIC INSULIN ASPART 30 OR BIPHASIC HUMAN INSULIN 30

Fakhoury W¹, Richter H², Christensen T³, Thomsen TL⁴, Irwin D⁵, Anderson P¹

¹IMS Health, London, UK, ²IMS Health GmbH & Co. OHG, Frankfurt am Main, Germany,

³Novo Nordisk, Virum, Denmark, ⁴Novo Nordisk A/S, Virum, Denmark, ⁵University of North Carolina—Chapel Hill, Chapel Hill, NC, USA

OBJECTIVES: The objective of this study was to compare glycaemic control and insulin utilisation in insulin naïve patients with type 2 diabetes (T2D) after initiation on biphasic insulin aspart 30 (BIAsp) or biphasic human insulin 30 (BHI) **METHODS:** A retrospective cohort study was conducted using the IMS Disease Analyzer a UK primary care database. Study inclusion required subjects to be insulin naïve with at least one prescription for an oral anti-diabetic agent (proxy for T2D diagnosis), 12 months history and follow up and treatment with either BIAsp or BHI. Patients with a diagnosis of type 1 diabetes were excluded. Glycemic control (HbA1c) was compared at baseline (-6 to 0 months) and at follow-up ($+6$ to 12 months). Average daily insulin dose (ADD) was compared at follow-up. Effect of age and sex as covariates on the difference in HbA1c and ADD between BIAsp and BHI was controlled for using ANOVA. **RESULTS:** Analyses were conducted on 630 BIAsp and 751 BHI patients on whom full data was available. The mean age for BIAsp patients was 61.6 years (59.7% men). For BHI, the mean age was 64.4 (51.9% men). From baseline to follow-up, the mean HbA1c for BIAsp dropped from 9.95% to 8.16% (change = 1.79%) and for BHI the HbA1c dropped from 10.34% to 8.62% (change = 1.72%). The HbA1c difference was borderline significant ($p = 0.07$). The ADD of BIAsp was 46.97 insulin units whereas the BHI ADD was 63.28 IU ($p < 0.01$). **CONCLUSIONS:** In this large retrospective analysis in insulin naïve patients initiated on pre-mixed insulin there was a trend towards better glycaemic control for users of BIAsp compared to BHI. Moreover, BIAsp was associated with a clinically relevant and statistically significantly lower ADD compared to BHI ($p < 0.01$). This has important implications for patient management and control of UK NHS costs.

PDB6

RELATIVE EFFECTIVENESS MANAGEMENT OF TYPE II DIABETES IN EUROPE: CAN THE AGENCIES' DEMANDS BE MET?

Hemels M¹, Jensen RCQ¹, Toumi M², Adalsteinsson E³

¹Novo Nordisk A/S, Bagsvaerd, Denmark, ²University Claude Bernard Lyon I, Villeurbanne Cedex, France, ³Novo Nordisk A/S, Soeborg, Denmark

OBJECTIVES: As decision-makers and the citizens they serve demand stronger evidence to support coverage, prioritization, and pricing, the need for relative effectiveness research has come to the fore. Whilst it is well known and documented that differences in costing structures, practise patterns and unit costs can lead to differences

in cost effectiveness estimates for any given clinical effect, less is known about the heterogeneity of treatments and their utilization to demonstrate Relative Effectiveness (RE) among EU countries. This study investigated differences in treatment availability and utilization using recommendations from HTA agencies as a proxy. **METHODS:** HTA reports were searched using 7 European HTA agencies websites (i.e., NICE, SMC, IQWiG, HAS, CAHTA, CVZ, TLV with the following keywords: pioglitazone, rosiglitazone, sitagliptin, vildagliptin, exenatide, glargine, detemir, aspart, glulisine and lispro. Recommendation was classified in three categories: recommended, restricted recommended, and not recommended in relation to indication based on marketing authorisation. **RESULTS:** No HTA agency had similar recommendations for all treatments. IQWiG recommended none of the products assessed (8), while Sweden recommended 86% of the products assessed (7). NICE, SMC, HAS, CAHTA and CVZ assessed 18, 8, 18, 15, and 10 products, recommending 22%, 50%, 56%, 13% and 0%, restricting 78%, 50%, 22%, 47% and 50% respectively. **CONCLUSIONS:** Large differences in recommendation of products among EU countries exist. As diabetes is a well established disease area, one would expect a more uniform armamentarium of recommended treatments. In light of the RE management plans, this research questions whether it is possible and desirable to develop a unified approach. Future research should focus on standardization of methods and address questions about acceptable methodology and its limitations.

PDB7

GLYCAEMIC CONTROL AND INSULIN UTILISATION IN PATIENTS WITH TYPE 2 DIABETES INITIATED ON A LONG-ACTING INSULIN ANALOGUE IN A DUTCH REAL-LIFE SETTING

Heintjes E¹, Thomsen TL², Penning FJA¹, Christensen T³, Herings RMC³

¹PHARMO Institute, Utrecht, The Netherlands, ²Novo Nordisk A/S, Virum, Denmark,

³PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands

OBJECTIVES: The objective of the study was to compare real-life glycaemic control, insulin utilisation and body weight in patients with type 2 diabetes initiated on insulin detemir (IDet) or insulin glargine (IGlar) and to discuss the results against treatment guidelines. **METHODS:** Patients with a history of oral anti-diabetic use starting treatment with IDet or IGlar from 2004 through 2006 were included in a retrospective cohort study using the Dutch PHARMO data network. Glycaemic control (HbA1c $< 7\%$) and daily insulin dose during unchanged insulin treatment up to 1 year of follow-up were compared between IDet and IGlar users using multivariate regression analysis adjusted for age, gender, propensity scores, baseline HbA1c and basal-bolus therapy. The observed results are discussed in context of European diabetes guidelines. **RESULTS:** A similar ($p = 0.44$) drop in HbA1c (from 8.6% to 7.5%) was observed for both IDet ($n = 199$) and IGlar ($n = 479$). Few patients were at goal at baseline (15.6% with IDet and 12.1% with IGlar). A similar proportion were at goal at follow-up (38.7% with IDet and 33.4% with IGlar) (adjusted OR 1.06; 95% CI 0.74:1.53). The average daily dose was similar at 29 IU/day (adjusted mean difference 0.2; 95% CI -2.9 :3.2). Median weight loss was 1 kg among IDet users and 0 kg among IGlar users, but this was not statistically tested due to low patient numbers. **CONCLUSIONS:** There was no significant difference between users of IDet and IGlar with respect to glycaemic control and insulin dose in a real-life setting in the The Netherlands. However, compared with treatment guidelines, the results showed few patients treated to target, which may indicate that basal insulin analogues are not titrated intensive enough or that rapid-acting insulin should be added to improve glycaemic control.

PDB8

FEWER TREATMENT CHANGES WITH PREMIXED INSULIN ANALOGUES COMPARED TO PREMIXED HUMAN INSULIN—A REAL-LIFE TREATMENT PATTERN ANALYSIS OF PATIENTS WITH TYPE 2 DIABETES IN THE NETHERLANDS

Thomsen TL¹, Heintjes E², Penning FJA², Christensen T¹, Herings RMC³

¹Novo Nordisk A/S, Virum, Denmark, ²PHARMO Institute, Utrecht, The Netherlands,

³PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands

OBJECTIVES: Studies suggest that premixed insulin analogues may improve the balance between glycaemic control and hypoglycaemia compared with human premixed insulin in type 2 diabetes (T2D) patients. This study aimed to observe prescription patterns of premixed insulin analogues compared to human premixed insulin among T2D patients. **METHODS:** Data for T2D patients starting premixed insulin in the period 2004–2006 were extracted from the Dutch PHARMO database. Patients were categorized into insulin naïve and prior insulin users. The proportion of patients changing treatment (discontinuing, adding fast-acting insulin or switching treatment) within one year was determined. Data was analyzed using Chi-Square tests for categorical data and t-tests for continuous data. **RESULTS:** The study included 3530 patients initiated on premixed insulin, of which 2324 (65.8%) were insulin naïve. Overall, 2134 (60.5%) started on analogues; the proportion of prescribed analogue insulin was greater among prior insulin users (812 of 1206 = 67.3%) vs. naïve users (1322 of 2324 = 56.9%). Patient characteristics did not differ between human insulin and analogue users, except from baseline HbA1c: in the group of prior users (1206 / 34.2%), a significant difference in baseline HbA1c was observed between those using human premixed insulin (8.5%) and premixed analogue (8.0%, $p < 0.001$). Within one year, 44.1% of human premixed users and 33.5% of premixed analogue users changed treatment. Among human premixed users 20.1% discontinued treatment (230 days), 6.5% added fast-acting insulin to their therapy (114 days), and 17.6% switched treatment (143 days); among premixed analogue users 14.9% discontinued treatment (245 days), 5.8% added fast-acting insulin (137 days), and 12.9% switched treatment